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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/316,199	05/21/99	MCCLUSKIE M	C1040/7006HC

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HELEN C LOCKHART
WOLF GREENFIELD & SACKS PC
600 ATLANTIC AVENUE
BOSTON MA 02210

EXAMINER	
NGUYEN, D	
ART UNIT	**PAPER NUMBER**
1633	11

DATE MAILED: 01/30/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/316,199	Applicant(s) MCCLUSKIE ET AL.	
	Examiner Dave Nguyen	Art Unit 1633	

-- The MAILING DATE of this communication appears on the cover sheet with th correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 December 1999* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29,47,66,73,77,81,85,89,93 and 109* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claims *1-29,47,66,73,77,81,85,89,93 and 109* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

The specification has been amended by the preliminary amendment filed December 6, 1999.

Claims 30-46, 48-65, 67-69, 70-72, 74-76, 78-80, 82-84, 86-88, 90-92, 94-108 and 110-124 have been canceled by the preliminary amendment filed December 27, 1999.

Claims 1-29, 47, 66, 73, 77, 81, 85, 89, 93 and 109, to which the following restriction requirement is applicable, are pending.

Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-28, drawn to a combination immunization method of employing an oligonucleotide and an antigen for inducing an mucosal immunity in a subject, wherein the oligonucleotide sequence has the following formula:

$$5'X_1X_2CGX_3X_4 3'$$

wherein C and G are unmethylated, wherein X1, X2, X3, and X4 are nucleotides, and wherein the antigen is not encoded in a nucleic acid vector, classified in Class 424, subclass 185.1.

Should Invention I be elected, claims 72, 80, 84, 88 and 92 will be examined to the extent that the breadth of the claims is encompassed by the elected Invention I.

II. Claims 29, drawn a combination immunization method of employing an CG containing plasmid and an antigen for inducing an mucosal immunity in a subject, wherein the plasmid has the sequence having at least the following formula:

$$5'X_1X_2CGX_3X_4 3'$$

wherein C and G are unmethylated, wherein X1, X2, X3, and X4 are nucleotides, and wherein the antigen is not encoded in a nucleic acid vector, classified in class 424, subclass 185.1, and class 514, subclass 44.

Should Invention II be elected, claims 29 will be examined to the extent that the breadth of the claims is encompassed by the elected Invention II.

III. Claims 29, drawn a combination immunization method of employing an CG containing plasmid and an antigen for inducing an mucosal immunity in a subject, wherein the plasmid has the sequence having at least the following formula:

$5'X_1X_2CGX_3X_43'$

wherein C and G are unmethylated, wherein X1, X2, X3, and X4 are nucleotides, and wherein the antigen is encoded in a nucleic acid vector, classified in class 514, subclass 44.

Should Invention IV be elected, claims 29, 33-46 and 76 will be examined to the extent that the breadth of the claims is encompassed by the elected Invention III.

IV. Claims 47, drawn a combination immunization method of employing an oligonucleotide and an antigen for inducing an mucosal immunity in a subject, wherein the oligonucleotide has the sequence including at least the following formula:

$5'X_1X_2CGX_3X_43'$

wherein C and G are unmethylated, wherein X1, X2, X3, and X4 are nucleotides, and wherein the antigen is encoded in a nucleic acid vector, classified in class 514, subclass 44.

Should Invention IV be elected, the claim will be examined to the extent that the breadth of the claims is encompassed by the elected Invention IV.

V. Claims 66, drawn to a combination immunization method of employing an oligonucleotide, an antigen and a hormone for inducing an mucosal immunity in a subject, wherein the oligonucleotide sequence has the following formula:

$5'X_1X_2CGX_3X_43'$

wherein C and G are unmethylated, wherein X1, X2, X3, and X4 are nucleotides, and wherein the antigen is not encoded in a nucleic acid vector, classified in Class 424, subclass 185.1.

Should Invention V be elected, claims 66 will be examined to the extent that the breadth of the claims is encompassed by the elected Invention V.

VI. Claims 66, drawn to a combination immunization method of employing an oligonucleotide, an antigen and a hormone for inducing an mucosal immunity in a subject, wherein the oligonucleotide sequence has the following formula:

$5'X_1X_2CGX_3X_43'$

wherein C and G are unmethylated, wherein X1, X2, X3, and X4 are nucleotides, and wherein the antigen is encoded in a nucleic acid vector, classified in Class 514, subclass 44.

Should Invention VII be elected, claims 66-68 will be examined to the extent that the breadth of the claims is encompassed by the elected Invention VI.

VII. Claims 77, 81, 85 and 89, drawn to a combination immunization method of employing an oligonucleotide and an antigen for inducing an immune response other than mucosal immunity immunity in a subject, wherein the oligonucleotide sequence has the following formula:

$5'X_1X_2CGX_3X_43'$

wherein C and G are unmethylated, wherein X1, X2, X3, and X4 are nucleotides, and wherein the antigen is not encoded in a nucleic acid vector, classified in Class 424, subclass 185.1.

Should Invention VII be elected, the claims will be examined to the extent that the breadth of the claims is encompassed by the elected Invention VII.

VIII. Claims 77, 81, 85 and 89, drawn to a combination immunization method of employing an oligonucleotide and an antigen for inducing an immune response other than mucosal immunity in a subject, wherein the oligonucleotide sequence has the following formula:

$5'X_1X_2CGX_3X_43'$

wherein C and G are unmethylated, wherein X1, X2, X3, and X4 are nucleotides, and wherein the antigen is encoded in a nucleic acid vector, classified in Class 514, subclass 44.

Should Invention VIII be elected, the claims will be examined to the extent that the breadth of the claims is encompassed by the elected Invention VIII.

IX. Claims 93 and 109, drawn to a combination immunization method of administering to a mucosal surface of a subject an oligonucleotide and an antigen for inducing a systemic immune in the subject, wherein the oligonucleotide sequence has the following formula:

$5'X_1X_2CGX_3X_43'$

wherein C and G are unmethylated, wherein X1, X2, X3, and X4 are nucleotides, and wherein the antigen is encoded in a nucleic acid vector, classified in Class 514, subclass 44.

Should Invention IX be elected, the claims will be examined to the extent that the breadth of the claims is encompassed by the elected Invention IX.

X. Claims 93 and 109, drawn to a combination immunization method of administering to a mucosal surface of a subject an oligonucleotide and an antigen for inducing a systemic immune in the subject, wherein the oligonucleotide sequence has the following formula:

$5'X_1X_2CGX_3X_43'$

wherein C and G are unmethylated, wherein X1, X2, X3, and X4 are nucleotides, and wherein the antigen is not encoded in a nucleic acid vector, classified in Class 514, subclass 44.

Should Invention X be elected, the claims will be examined to the extent that the breadth of the claims is encompassed by the elected Invention X.

XI. Claims 73, drawn a combination immunization method of employing an CG containing plasmid and an antigen for inducing any immune response in a subject, wherein the plasmid is administered orally and has the sequence having at least the following formula:

$5'X_1X_2CGX_3X_43'$

wherein C and G are unmethylated, wherein X1, X2, X3, and X4 are nucleotides, and wherein the antigen is not encoded in a nucleic acid vector, classified in class 424, subclass 185.1, and class 514, subclass 44.

XII. Claims 73, drawn a combination immunization method of employing an CG containing plasmid and an antigen for inducing any immune response in a subject, wherein the plasmid is administered orally and has the sequence having at least the following formula:

$$5'X_1X_2CGX_3X_43'$$

wherein C and G are unmethylated, wherein X1, X2, X3, and X4 are nucleotides, and wherein the antigen is encoded in a nucleic acid vector, classified in class 424, subclass 185.1, and class 514, subclass 44.

The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods constitute patentably distinct inventions for the following reasons: Inventions I to XII are directed to different goals and comprises materially distinct steps. The materials and method steps in each of the invention comprise distinct product and steps, respectively, in order to generate a end result as intended by the preamble of each of the elected invention. For example, the use of antigens not encoded in a vector is not equivalent to that of nucleic acid vectors encoding an antigen. In addition, an administration of simple oligonucleotides is distinct as compared to that of CG containing plasmid, which may encompasses the use of any other expression cassette that encodes an additionally therapeutically relevant product. Furthermore, immunization methods for eliciting an mucosal immunity in any subject by using any route of administration is distinct from immunization methods of employing an antigen not encoded in a vector for simple generation of an immune response (B cell response or cellular response) other than mucosal immunity. Each of the Inventions I to XI requires distinct prior art search and consideration of patentability with respect to the state of the prior art as a whole.

Should Invention I, II, III, IV, V, VI, VII, VIII, IX, X, XI or XII, be elected, the base claims are generic to a plurality of disclosed patentably distinct species comprising a specific CpG-N motif as follows:

5'$X_1X_2CGX_3X_4$3'

wherein X_1, X_2, X_3, and X_4 must be clearly defined as specific nucleotide residues, *e.g.*, A, T, C, or G.

Applicant is further required under 35 U.S.C. 121 to elect a single disclosed species as specified above, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Should Invention I, II, III, IV, V, VI, VII, VIII, IX, X, XI or XII be elected, the base claims are generic to a plurality of disclosed patentably distinct species comprising a specific colloidal dispersion system as recited as a Markush group in claim 6, for example

Applicant is further required under 35 U.S.C. 121 to elect a single disclosed species as specified above, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Should Invention I, II, III, IV, V, VI, VII, VIII, IX, X, XI or XII be elected, and should the lipid-based system is elected as a species of colloidal dispersion system, the claims of the elected invention are generic to a plurality of disclosed patentably distinct species comprising a specific lipid-based system as recited as a Markush group in claim 7, for example

Applicant is further required under 35 U.S.C. 121 to elect a single disclosed species as specified above, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Should Invention I, II, III, IV, V or VI be elected, the claims of the elected invention are generic to a plurality of disclosed patentably distinct species comprising a specifically claimed non-oligonucleotide mucosal adjuvant as recited as a Markush group in claim 9, for example

Applicant is further required under 35 U.S.C. 121 to elect a single disclosed species as specified above, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Should Invention I, II, III, IV, V, VI, VII, VIII, IX, X, XI or XII be elected, the claims of the elected invention are generic to a plurality of disclosed patentably distinct species comprising a subject that is subjected for immunization, *e.g.,* see claims 11, 12, 13 and 23, for example

Applicant is further required under 35 U.S.C. 121 to elect a single disclosed species as specified above, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Should Invention I, II, III, IV, V, VI, VII, VIII, IX, X, XI or XII be elected, the claims of the elected invention are generic to a plurality of disclosed patentably distinct species comprising a specifically employed antigen, *e.g.,* see claim 22, for example

Applicant is further required under 35 U.S.C. 121 to elect a single disclosed species as specified above, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Should Invention I, II, III, IV, V, VI, VII, VIII, IX, X, XI or XII be elected, the claims of the elected invention are generic to a plurality of disclosed patentably distinct species comprising a specifically employed route of administration of the antigen and the oligonucleotide or the CG containing plasmid, *e.g.,* see claims 73, 77, 81, 85 and 89, for example

Applicant is further required under 35 U.S.C. 121 to elect a single disclosed species as specified above, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their divergent subject matter, fall into different statutory classes of invention, and are separately classified and searched, restriction for examination purposes as indicated is proper, particularly it would be unduly burdensome for the examiner to search and examiner all of the subject matters set forth in all of presently pending claims.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Any inquiry concerning this communication or earlier communications regarding the formalities should be directed to Patent Analyst Kimberly Davis, whose telephone number is **(703) 305-3015**.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner *Dave Nguyen* whose telephone number is **(703) 305-2024**.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *Deborah Clark*, may be reached at **(703) 305-4051.**

Any inquiry of a general nature or relating to the status of this application should be directed to the *Group receptionist* whose telephone number is **(703) 308-0196**.

Dave Nguyen
Patent Examiner
Art Unit: 1633